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ICD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,861 02/11/00 RICCIARDI

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HM12/0808

EXAMINER

BROWDY AND NEIMARK
624 NINTH STREET
WASHINGTON DC 20004

EPPS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

08/08/01
16

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/403,861	RICCARDI, CARLO
	Examiner	Art Unit
	Janet L. Epps	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 July 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14,24 and 26-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-10,13,14,24 and 27-40 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11,12 and 26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 February 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 11-12 and 26 in Paper No. 15, received 7-18-01 is acknowledged.
2. Claims 1-10, 13-14, 24, 26-30, and 32-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Drawings

3. The drawings filed 2-11-2000 are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons set forth in the attached PTO-948.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-12 and 26, recite the limitation "a DNA sequence according to claim 1." This phrase is vague and indefinite since claim 1 is withdrawn as being drawn to a non-elected invention in Paper No. 15.

Claims 11-12, and 26 recite the limitation "[a] GILR protein or derivatives thereof encoded by a DNA sequence according to claim 1." Although, claim 1 is not part of the

elected invention, if the limitations of claim 1 where incorporated into claim 11, claim 11 would be limited to a DNA sequence comprising SEQ ID NO:1. However, if the term "derivatives thereof" is interpreted broadly, it would encompass GILR proteins other than those encoded by the sequence according to SEQ ID NO:1. Furthermore, claim 12 recites "wherein said protein and derivatives have at least part of the amino acid sequence SEQ ID NO: 2 or of the amino acid sequence SEQ ID NO:5." This limitation is vague and indefinite since the breadth of this limitation encompasses sequences other than those encoded by SEQ ID NO: 1.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-12 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using a GILR protein comprising the amino acid sequence according to SEQ ID NO:2 and 5, does not reasonably provide enablement for making and using GILR protein derivatives wherein said GILR protein derivatives are capable of inhibiting apoptosis and stimulating lymphocyte activity . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims read on a GILR protein and derivatives thereof, and further wherein said derivatives have at least a part of the amino acid sequence of SEQ ID

Art Unit: 1635

NO:2 or 5. The claimed GILR protein and derivatives thereof are capable of inhibiting apoptosis and stimulating lymphocyte activity. It is noted that the instant rejection is applied since claims 11-12 and 26 are vague and indefinite as described above, and to the extent that the instant claims encompass sequences other than those encoded by SEQ ID NO:1, or other than those comprising a sequence according to SEQ ID NO: 2 or 5.

According to the specification as filed, the term derivatives "covers derivatives which may be prepared from the functional groups which occur as side chains on the residues or the N- or C-terminal groups, by means known in the art, and are included in the invention. Derivatives may have chemical moieties such as carbohydrate or phosphate residues, provided such a fraction has the same or higher biological activity as GILR proteins." Furthermore, the specification states that "derivatives may be prepared by standard modifications of the side groups of one or more amino acid residues of the GILR protein, its analogs or fragments, or by conjugation of the GILR protein, its analogs or fragments, to another molecule e.g. an antibody, enzyme, receptor, etc." (Specification page 33, lines 1-18). Therefore, based upon applicant's definition of the term "derivatives" encompasses a broad genus of molecules including modified analogs or fragments of the GILR proteins of the present invention.

Additionally, claim 12 recites wherein, the GILR protein and derivatives thereof "have at least part of" the amino acid sequences SEQ ID NO: 2 or 5.

The specification as filed does not provide sufficient guidance and/or instruction that would allow one of skill in the art to predict the structure of all the members of the

claimed genus of derivatives of the GILR protein which have at least part of the amino acid sequence of SEQ ID NO: 2 or 5, wherein said derivatives are capable of inhibiting apoptosis and stimulating lymphocyte activity. The only structures that are clearly disclosed as having the capability of inhibiting apoptosis and stimulating lymphocyte activity are those amino acids comprising a sequence according to SEQ ID NO: 2 or 5. The instant claims encompasses structures other than those structures according to SEQ ID NO: 2 and 5, however Applicants have not provided any instructions regarding how GILR protein derivatives are to be made wherein said derivatives maintain the capability of inhibiting apoptosis and stimulating lymphocyte activity. Neither the specification nor the claims indicate what distinguishing attributes are shared by all members of the claimed genus of GILR protein derivatives that are capable of inhibiting apoptosis and stimulating lymphocyte activity. The disclosure fails to describe the common attributes or characteristics that identify all members of the claimed genus of GILR protein derivatives according to the instant invention. One of skill in the art would have to resort to trial and error experimentation in order to determine the structures of all the GILR protein derivatives encompassed by the claimed genus that maintain the desired functionality.

In regards to the level of unpredictability in the art of polypeptide modification, the prior art teaches that subtle changes to the structure of a polypeptide can drastically affect the normal catalytic function of a polypeptide. For example, Herrmann et al. teach that elongation of the *N*-acyl side chain of the siliac acid on the murine polyomavirus receptor on the surface of cells rendered the receptor inactive for use in

Art Unit: 1635

infection and high-affinity binding. The addition of one methylene group to the *N*-acyl side chain of siliac acid result in steric hindrance in the vicinity of the binding surface of the receptor, thereby preventing binding interactions (page 5929, paragraph 7). The teachings of Herrmann et al. clearly indicate that subtle protein modifications can result in a drastic change in protein function.

In light of the breadth of the claimed invention, the number of modifications encompassed by the GILR protein derivatives according to the claimed invention, the lack of guidance regarding how to make the GILR protein derivatives which are capable of inhibiting apoptosis and stimulate lymphocyte activity, and further with the amount of experimentation required to make and use the claimed GILR protein derivatives, it is concluded that undue experimentation would be required to practice the full scope of the claimed invention. Therefore, the specification as filed does not allow one of skill in the art to make and use the full scope of the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-12 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibanuma et al. and Jay et al.

The instant claims are interpreted as reading on a GILR protein or derivatives comprising at least part of the amino acid sequence according to SEQ ID NO: 2, or 5, and encoding at least one active human GILR protein. It is also noted that applicants do not clearly define the intended meaning of the term "have at least part of" with regards to SEQ ID NO: 1, 2, or 5. Additionally, the term "pharmaceutical" recited in claim 26 is not given any patentable weight for prior art purposes, claim 26 is interpreted as reading on a composition comprising at least one GILR protein or its biologically active derivatives or mixtures thereof.

The prior art clearly discloses that members of the GILR family of leucine zipper proteins share a high degree of sequence homology between members of the protein family. Shibanuma et al. and Jay et al. disclose proteins sharing at least part of the DNA sequence of SEQ ID NO: 1, 2, or 5, and further encoding a leucine zipper family related protein.

Shibanuma et al. disclose the mouse TSC-22 leucine zipper containing protein. This is a protein of 143 amino acids, and comprises 89 identical residues of the GILR protein according to SEQ ID NO: 2 of the instant application. Therefore Shibanuma et al. disclose a protein comprising at least part of a protein according to SEQ ID NO: 1, 2, or 5 according to the instant application.

Jay et al. disclose the human TS-22 leucine zipper containing protein. The TS-22 protein comprises a sequence that is 70% identical to the polypeptide according to SEQ ID NO: 2 of the instant application. Therefore the polypeptide of Jay et al. clearly comprises at least a part of the GILR proteins of the instant application.

Art Unit: 1635

Therefore, Shibanuma et al. and Jay et al. teach each and every aspect of the instant application thereby anticipating applicant's claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Janet L Epps
Examiner
Art Unit 1635

jle
August 7, 2001